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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/974,882 | 10/10/2001 | Edward M. Nolan | GTI-1320-CON1 | 8790 |
| 35938 | 7590 | 10/22/2003 | EXAMINER | |
| BIOTECHNOLOGY LAW GROUP | | | SULLIVAN, DANIEL M | |
| 658 MARSOLAN AVENUE | | | ART UNIT | PAPER NUMBER |
| SOLANA BEACH, CA 92075 | | | 1636 | |

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,882

Applicant(s)

NOLAN ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Non-Final Office Action is a reply to the "Amendment and Response to Office Action" filed 22 September 2003 (hereinafter, 22 September Reply) filed in response to the Final Office Action mailed 18 March 2003 (hereinafter, 18 March Office Action). Claims 21, 24 and 25 were considered in the 18 March Office Action. Claims 1-20, 22 and 23 were canceled and claim 26 was added in the 22 September Reply. Claims 21 and 24-26 are pending and under consideration.

Response to Arguments

Oath/Declaration

The objection to the Declaration is withdrawn in view of the clarification provided.

Claim Rejections - 35 USC § 103

Rejection of claims 21 and 24 under 35 U.S.C. §103 is withdrawn in view of Applicant's arguments.

New Grounds

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an

application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Please note, if the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application (see 37 CFR § 1.78(a)(2) and (a)(5)). This time period is not extendable and a failure to submit the reference required by 35 USC § 119(c) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 USC § 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 USC 119(c), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR § 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional.

Although Applicant claims in the 22 September Reply that a document amending the first line of the specification to include the chain of priority was filed with the application, the Examiner can find no such amendment in the file (see attached interview summary). Therefore, Applicant must provide evidence that the specification was timely amended to include a reference to the priority document or file a petition as indicated herein above.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Although the specification recites certain species of cells that are not plant cells, there is no basis for the broad negative limitation "wherein said cell is not a plant cell" in the specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/34436 (hereinafter, '436).

Because the priority claim under 35 U.S.C. §120 has not been perfected (*Id.*), the instant claims are afforded a filing date of 10 October 2001, which is greater than one year after the publication of '436. The '436 publication therefore qualifies as prior art under 35 U.S.C. §102(b).

The '436 publication teaches a method for introduction of at least one chromosome into a eukaryotic cell comprising contacting at least one chromosome substantially simultaneously with the application of an electric pulse to the cell, wherein the chromosome is encapsulated in a liposome or micell (see especially claims 21 and 22). The '436 publication further teaches that the cells can be fibroblasts, parenchymal stem cells or hematopoietic stem cells, which are not plant cells (see especially the paragraph bridging pages 8-9). Thus, the '436 publication teaches

all of the limitations of claim 21. Further, the '436 publication teaches the method wherein transformation of the cell with at least one chromosome is verified by FACS according to the limitations of claims 24-26 (see especially the paragraph bridging pages 9-10). The '436 publication teaches a method comprising all of the limitations of the instant claims; therefore, the claims are anticipated by the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS


DANIEL M. SULLIVAN
PRIMARY EXAMINER